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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,626	08/04/2006	Philip Savage	30699/42250	7227
4743	7590	11/16/2007		
MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER WILSON, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1632	
			MAIL DATE	DELIVERY MODE
			11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/588,626	<b>Applicant(s)</b> SAVAGE, PHILIP	
	<b>Examiner</b> Michael C. Wilson	<b>Art Unit</b> 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-37 are pending.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to a method of damaging cells using DNA encoding alcohol dehydrogenase and ethanol and an inhibitor of aldehyde dehydrogenase (e.g. Disulfiram), classified in class 514, subclass 44, et al.
- II. Claims 1 and 4-14, drawn to a method of damaging cells using DNA encoding alcohol dehydrogenase and ethanol and radiation, classified in class 514, subclass 44, et al.
- III. Claims 15 and 16, drawn to DNA encoding alcohol dehydrogenase, classified in class 536, subclass 23.1.
- IV. Claims 17 and 18, drawn to DNA encoding alcohol dehydrogenase combined with an inhibitor of aldehyde dehydrogenase, classified in class 536, subclass 23.1, et al.
- V. Claim 19, drawn to DNA encoding alcohol dehydrogenase combined with chemotherapeutic agent, classified in class 536, subclass 23.1, et al.
- VI. Claim 20, drawn to DNA encoding alcohol dehydrogenase combined with an immunosuppressive agent, classified in class 536, subclass 23.1, et al.

- VII. Claims 24 and 25, drawn to DNA encoding alcohol dehydrogenase combined with ethanol and an inhibitor of aldehyde dehydrogenase, classified in class 536, subclass 23.1, et al.
- VIII. Claim 22, drawn to a method of treating cancer using DNA encoding alcohol dehydrogenase, classified in class 514, subclass 44.
- IX. Claim 23, drawn to a method of treating cancer by administering ethanol or pyruvate, classified in an unknown class and subclass.
- X. Claim 28 and 33, drawn to DNA encoding alcohol dehydrogenase combined with a chemotherapeutic agent and an immunosuppressive agent, classified in class 536, subclass 23.1, et al.
- XI. Claims 29 and 30, drawn to DNA encoding alcohol dehydrogenase combined with an inhibitor of aldehyde dehydrogenase, classified in class 536, subclass 23.1, et al.
- XII. Claim 31 and 32, drawn to DNA encoding alcohol dehydrogenase combined with an inhibitor of aldehyde dehydrogenase and an immunosuppressive agent, classified in class 536, subclass 23.1, et al.
- XIII. Claims 34 and 35, drawn to a method of treating cancer using DNA encoding alcohol dehydrogenase combined with an inhibitor of aldehyde dehydrogenase, classified in class 514, subclass 44, et al.
- XIV. Claim 36, drawn to a method of DNA encoding alcohol dehydrogenase combined with a chemotherapeutic agent, classified in class 514, subclass 44, et al.

- XV. Claim 37, drawn to a method of treating cancer using DNA encoding alcohol dehydrogenase combined with an immunosuppressive agent, classified in class 514, subclass 44, et al.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, VIII, IX, XIII, XIV and XV (methods) are patentably distinct from Groups III-VII and X-XII (compositions) because the methods are used to treat cancer while the compositions can be used to simply express alcohol dehydrogenase in vitro. Some inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the composition can be used to express alcohol dehydrogenase in vitro or to damage cells in vitro. The composition does not have to be used in vivo, specifically to treat cancer.

Groups III-VII and X-XII are patentably distinct because the compositions have different structures and different functions. DNA alone can be used as a probe while DNA combined with an inhibitor of aldehyde dehydrogenase can be used to damage a cell while DNA combined with chemotherapeutic agents can be used to treat cancer. The burden required to search all the combinations together would be undue.

Groups I, II, VIII, IX and XIII-XV are patentably distinct because the methods require different compositions that have different structures and different functions. DNA alone can be used as a probe while DNA combined with an inhibitor of aldehyde

dehydrogenase can be used to damage a cell while DNA combined with chemotherapeutic agents can be used to treat cancer. The burden required to search all the combinations together would be undue.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/  
Patent Examiner